Liza M. Walsh
Katelyn O'Reilly
Selina M. Ellis
Walsh Pizzi O'Reilly Falanga LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100

Attorneys for Plaintiffs
Teva Branded Pharmaceutical
R&D Inc. and Norton (Waterford) Ltd.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL	:	Consolidated Civ. Action No.
	:	20-10172 (JXN) (MAH)
PRODUCTS R&D, INC., and	:	
NORTON (WATERFORD) LTD.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
CIPLA LTD., AUROBINDO PHARMA	:	
LLC, AUROBINDO PHARMA USA,	:	
INC., and AUROLIFE PHARMA LLC,	:	
	:	
Defendants.	:	
	:	

PLAINTIFFS TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. AND NORTON (WATERFORD) LTD.'s POSTTRIAL BRIEF ADDRESSING VALIDITY

Table of Contents

Table of Authorities

Cases

Statutes

I. Introduction

Cipla failed to prove invalidity by clear-and-convincing evidence, a legal burden Cipla's brief never once acknowledges. That omission is no accident. Rather than confront the steep hill it must climb to prove each of Teva's patents obvious, Cipla relies principally on the testimony of its expert, Mr. Anderson, whose assertions were so conclusory as to be entitled to no legal weight. His *ipse dixit* opinions were devoid of analysis, contradicted by prior testimony, and untethered to the legal standards.

Even accepting Mr. Anderson's testimony at face value, however, Cipla's invalidity case falls far short of meeting its clear-and-convincing burden. Cipla previously asserted more than 1,000 obviousness theories as well as anticipation, enablement, written description, and indefiniteness defenses. At trial, Cipla abandoned all but three theories—none is a winner. With respect to the '289 and '587 Patents, Cipla, fatally, could not identify *any* teaching, *anywhere* in the prior art, reflecting the critical "Common Plane" limitation. The same was true of the '808 Patent's requirement for a "regulator" with a "resistance force" of "greater than 0.3 N." Facing a dearth of evidence, Cipla resorted to hindsight-laden analyses that failed to grapple with the cited prior art, much less the prior art as a whole.

On this record, Teva could have remained silent and prevailed. Teva did not do so. Instead, Dr. Lewis testified emphatically that the POSA would *not* have pursued the combinations of references Cipla asserts, would *not* have had a reasonable expectation of success in doing so, and would *not* have achieved the claimed inventions in any event.

Cipla failed to prove obviousness, and its invalidity defense fails.

II. Legal Standards

"A patent is presumed valid, and the burden of establishing invalidity of a claim rests on the party asserting invalidity by clear and convincing evidence." *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1364 (Fed. Cir. 2018). That is the highest standard of proof in a civil case, and it follows from the statutory presumption of validity. 35 U.S.C. § 282. If the challenger fails to prove invalidity by that standard, the patentee is entitled to judgment of validity. *Id.* This is the case *even were the patentee to offer no affirmative rebuttal*. *See Core Wireless*, 880 F.3d at 1363-64.

Proof of obviousness requires a challenger to demonstrate that the POSA (1) would have had a reason or motivation to combine the teachings of the prior art in a manner that achieved the claimed invention, and (2) would have had a reasonable expectation of success in doing so. *Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1271 (Fed. Cir. 2018). Motivation and expectation are "two different legal concepts" and thus two independent barriers to success—failure to prove either is fatal to an obviousness claim. *Endo Pharms. Inc. v. Actavis LLC*, 922 F.3d 1365, 1376 n.11 (Fed. Cir. 2019) (declining to consider motivation issues where challenger failed to prove reasonable expectation of success); *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (testimony that POSA "*could* combine" references insufficient to prove obviousness absent motivation).

Given the high burden patent challengers face, more than mere *ipse dixit*

assertions of motivation and expectation are required. *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019). To that end, the Federal Circuit consistently rejects "obviousness determinations based on conclusory and unsupported expert testimony" because "crediting such testimony risks allowing the challenger to use the challenged patent as a roadmap to reconstruct the claimed invention using disparate elements from the prior art." *Id.*

III. The Asserted Claims of the '289 Patent Would Not Have Been Obvious

Teva's inventors contributed a key discovery to the field of metered dose inhaler (MDI) dose counters—they recognized that they could improve counter accuracy by lining up three elements of the MDI: (1) the center of the central outlet port of the in the inhaler body, and (2) an actuation member of the dose counter, and (3) an inner wall canister support formation of the inhaler body. Findings of Fact ("FOF") 46. That contribution, unknown in the prior art, is enshrined in the "Common Plane Limitation" and thus a feature of each asserted claim in the '289 Patent. JTX-003.[1]

Since this case began, including in the pretrial order, Cipla argued that a single reference—the '406 Publication—disclosed every limitation of Claim 1. D.E. 210, at 16. At trial, that theory was abandoned. Cipla now formally concedes that the '406 Publication does *not* teach the Common Plane Limitation, nor does it have *any* inner

[1] The Common Plane Limitation recites: "the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X [which passes through the center of the central outlet port]."

wall canister support formations. Br. 29. Instead, Cipla argues that the POSA would have plucked support rails out of a different publication—the '514 Publication—and added them to the MDI of the '406 Publication, lined up in a way that coincidentally meets the Common Plane Limitation. There is simply no reason (aside from hindsight) that the POSA would have combined these references at all, given their contradictory approaches to dose counting, let alone done so in the manner Cipla claims.

Cipla's expert failed to grapple with these issues. His testimony was untethered to the references in Cipla's theory and devoid of explanation. Dr. Lewis, by contrast, examined the references carefully and explained why their conflicting principles foreclosed Cipla's hindsight-infected combination of the '406 and '514 Publications.

A. Cipla Agrees Teva's Inventions Are New

Cipla now acknowledges that at the time of Teva's inventions,[2] no inhaler body known or described *anywhere* in *any* publication *in the world* disclosed those inventions. FOF 47. As of May 2010, no MDI existed in which an actuation member of the dose counter was aligned in a common plane with an inner wall canister support formation and the center of the central outlet port. *Id.* It is thus undisputed that Teva's inventions were new, and Cipla has completely abandoned any argument that Teva's inventions are invalid for anticipation. *See* 35 U.S.C § 102; FOF 47-48.

Cipla agrees that *neither* the '406 Publication *nor* the '514 Publication discloses an

[2] The '289 Patent claims priority to an application filed May 18, 2010. Teva need prove an earlier invention date, because there is no dispute Cipla's references are prior art.

inhaler that meets the Common Plane Limitation, but argues instead that the POSA would have surveyed the sea of prior art describing MDIs, plucked out both the '406 and '514 Publication—and no others—and combined them in ways that just so happen (in Cipla's view, but no one else's) to produce an inhaler that meets the Common Plane Limitation. FOF 48. That is pure hindsight, and must be rejected.

B. Cipla Failed to Prove that the Asserted Claims Would Have Been Obvious to the POSA In View of the '406 and '514 Publications

Cipla offered only a single theory of invalidity—namely, that the POSA would have found it obvious to add the support rails of the '514 Publication to the inhaler and dose counter of the '406 Publication. FOF 48. To prove this theory, Cipla was required to establish, by clear-and-convincing evidence, that the POSA would have been motivated to add the specific support rails (but only the support rails) disclosed in the '514 Publication to the specific inhaler body and dose counter of the '406 Publication, *and* would have been motivated to align at least one such rail according to the Common Plane Limitation. Cipla *also* was required to marshal clear-and-convincing evidence that the POSA would have had a reasonable expectation of success in combining those two specific Publications in the manner claimed. Cipla fell short at every step. FOF 49.

1. Cipla Failed to Prove That the POSA Would Have Been Motivated to Combine the '406 and '514 Publications

Cipla offered evidence of alleged obviousness through a single witness—its expert, Mr. Anderson. FOF 48. Mr. Anderson's testimony regarding the POSA's motivation to combine the '406 and '514 Publications was fatally flawed for a multitude

of reasons, each of which is independently sufficient to doom Cipla's case. FOF 50.

a. Cipla Failed to Prove that the POSA Would Have Plucked the '406 and '514 Publications Out of the Sea of Prior Art as a Desirable Combination

Cipla argues that to prove obviousness, it need not establish that the POSA would have selected the '406 Publication and '514 Publication for combination. Br. 42 (citing *Novartis Pharms. Corp. v. West-Ward Pharms. Int'l*, 923 F.3d 1051, 1059-60 (Fed. Cir. 2019)), 44 (citing cases that combination need not be "most desirable"). Cipla misses the point. While a combination need not be "*the preferred, or the most desirable*, combination," *Novartis*, 923 F.3d 1059 (emphasis added), it need be at least, "on balance, desirable." *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 (Fed. Cir. 2000); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 US 398, 418 (2007). Cipla failed to prove even that, and so fails to meet its burden to show "a contemporaneous reason in the prior art to make the claimed invention." *KSR*, 550 US at 418.

It is axiomatic that proof of obviousness requires proof of a motivation to combine the particular references identified. "[W]hether a [POSA] would be motivated to make a combination *includes whether he would select particular references in order to combine their elements*." *WBIP, LLC v. Kohler Co.,* 829 F.3d 1317, 1337 (Fed. Cir. 2016) (emphasis added). "Too often the obviousness analysis is framed as an inquiry into whether a [POSA], with two (and only two) references sitting on the table in front of him, would have been motivated to combine . . . the references in a way that renders the claimed invention obvious." *Id.* "*The real question is whether that [POSA] would have plucked one*

reference out of the sea of prior art . . . and combined it with [elements of a second reference] to address some need present in the field." *Id.* (emphasis added). Accordingly, Cipla *must* demonstrate that the POSA would have considered the specific references in question as a suitable starting point for modification—*i.e.*, that the POSA "would have plucked the [MDI of the '406 Publication] out of the sea of prior art . . . and combined it with [the ribs of the '514 Publication]." *Id.* No case relieves Cipla of this burden, the law's fundamental guardrail against improper hindsight. *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017) (requiring reason to combine "these particular references"); *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998) (forbidding hindsight in selection of art).

Even though Cipla bore the burden of proving this issue by clear-and-convincing evidence, Mr. Anderson never addressed it. He simply assumed (contrary to controlling law) that his preferred references could be plucked from the sea without basis. FOF 53-54. Dr. Lewis explained that the POSA would have faced a number of design choices and a wide range of dose indicators and counters and support rails from which to choose, FOF 51-52, and would have been led *away* from the combination of the '406 and '514 Publication at every turn, FOF 55. His testimony was supported in this respect by DTX-148, a publication by Adam Stuart, an inventor of the '406 Publication. *Id.* As Dr. Lewis explained, the 2013 Stuart article reflects the state of the art in 2010 and the design choices the POSA would have faced as of Teva's invention date. *Id.*

First, Dr. Lewis testified that—in order to maximize the chance of successfully designing an accurate product—the POSA would have preferred to make or modify a

(simpler) dose indicator rather than a (complicated) dose counter, and therefore would have avoided working with the dose counter of the '406 Publication. FOF 58-61.

Second, Dr. Lewis explained that, even had the POSA pursued a dose counter, the POSA would have had to decide *where* to locate it. FOF 62. But, the POSA would have *avoided* squeezing the counter *inside* the inhaler body (like the '406 Publication does). FOF 63-64 ("Anything inside I wouldn't be thinking of. I would be avoiding that."). The POSA would have prioritized medication delivery above all else, and would have avoided internal counter placements that risked altering airflow and delivery. FOF 64-65 ("I wouldn't do that. . . . You will change the medication."). Indeed, this is why an inventor of the '406 Publication continued to emphasize the problems with placing a dose counter inside the inhaler body years *after* the '406 Publication—his article did not suggest that the '406 Publication had solved such problems. FOF 66 ("Stuart is highlighting if we're going to keep drug delivery consistent, don't put it inside the upflow."); *contra* Br. 45 (attorney argument only). The POSA would have mounted the dose counter on the top or side of the inhaler, to avoid changing delivery and increase space for counter components. FOF 62-67. The POSA would have avoided the '406 Publication's internal counter—Mr. Anderson said not one word to the contrary. *Id.*

Third, even if the POSA (1) chose to make a dose counter, and (2) chose to place that counter inside the inhaler body, the POSA would have chosen to *affix the dose counter to the medication canister*. FOF 68-73. As Dr. Lewis explained, affixing the counter to the canister simplifies counting because "you don't have to solve the rocking

problem." FOF 71. As of May 2010, the POSA would have known that only one inhaler on the market had an internal dose counter, and this product affixed its counter to the canister. FOF 70. The '406 Publication does not affix its counter to the canister, and the POSA would have avoided it for that reason as well. FOF 72.

Thus, at every fork in the design road, the POSA would not merely have found other paths preferable, but would have *avoided* selecting the '406 Publication for combination with the '514 Publication. FOF 55-73. Cipla argues—without support from Mr. Anderson's testimony—that "big name" 3M authored the '406 Publication, making it attractive to the POSA. Br. 43. Dr. Lewis agreed that 3M was an impressive company, to be sure, but explained that the '406 Publication was cleverly designed in a way that depended on using its specific components. FOF 74. The POSA who wished to *alter* 3M's design (as required to arrive at Teva's invention) would have viewed the '406 Publication as a non-starter.[3] FOF 74; Tr. 747:21-748:3 ("[T]he specific '406 [Publication] makes it difficult to move to different components by its very design.").

Indeed, Dr. Lewis's testimony that the POSA would have avoided the '406 Publication went entirely unrebutted. FOF 53-54. Mr. Anderson did not offer *any*

[3] Dr. Lewis expressed his admiration for Mr. Stuart and the '406 inventors, calling their design "fantastic." FOF 75. As he made clear, the "fantastic" part of the '406 Publication is its clever stabilization of the canister via a fit between the valve and the dose counter. *Id.* Dr. Lewis was *equally* clear that modifying its design by adding rails would destroy that elegant solution, and would not have been "fantastic" at all. *Id.* ("[N]ot a good idea"). In other words, the '406 Publication might be "fantastic" in isolation, but was not a "fantastic" starting point for the change Cipla has suggested. *Id.* The POSA intending to add ribs would have *avoided* the '406 Publication. *Id.*

reason why the POSA would have "plucked" the '406 Publication out of the sea of prior art dose counters, as the law requires. *Id.*; *WBIP,* 829 F.3d at 1337. Instead, when cross-examined regarding his reason for selecting the '406 Publication, Mr. Anderson conceded, candidly and fatally, that it was just "the one that we're talking about as far as the dose counters are concerned." FOF 54 ("Q. Any other reason? A. No."). Mr. Anderson's opinion began with the '406 Publication *not* because he believed (or even considered whether) the POSA would have identified it as a desirable starting point, but rather because it most closely resembled the claims he set out to invalidate. The Federal Circuit "forbids the use of hindsight in the selection of references that comprise the case of obviousness." *Rouffet*, 149 F.3d at 1358. This Court should do the same. Had the POSA not selected Mr. Anderson's hindsight-picked references, the POSA would not have arrived at the claimed invention. Cipla's case thus fails. FOF 56-57.

b. Cipla Failed to Prove that the POSA Would Have Been Motivated to Add Support Rails to the '406 Publication

Even if the POSA (1) chose to make a dose counter rather than a dose indicator, (2) chose to locate the counter internally rather than outside the inhaler body, (3) chose *not* to affix the counter to the canister, and (4) viewed the '406 Publication as a suitable starting point—and to be clear, Dr. Lewis testified without contradiction from Mr. Anderson that the POSA *would not have made any of these choices*—Cipla still failed to establish by clear-and-convincing evidence that the POSA would have had a reason to *add support rails* to the inhaler of the '406 Publication. FOF 76. It is undisputed that if

the POSA did not have a reason to add support rails to the inhaler body of the '406 Publication, the POSA would not have arrived at the claimed invention. FOF 86.

Mr. Anderson testified as to general benefits of support ribs in MDIs. FOF 78. According to Mr. Anderson, "[i]t doesn't cost you anything to add a rib, so why wouldn't you put it in to enhance the product." Tr. 575:2-4. He also testified that ribs were ubiquitous, and that "if you look at any MDI, any puffer body, they have got ribs in them." *Id.* at 576:2-4; FOF 77. Neither theory passes muster.

Mr. Anderson's generalized testimony regarding advantages of ribs was untethered to the '406 Publication. FOF 78, 80. That is a fatal lapse under the law, and reveals the superficial nature of Mr. Anderson's analysis. *ActiveVideo Networks v. Verizon Comm'ns*, 694 F. 3d 1312, 1328 (Fed. Cir. 2012) (generic motivation to "build something better" insufficient). Contrary to Mr. Anderson's assertion, it plainly is *not* true that "any MDI" has ribs—the MDI of the '406 Publication does not. FOF 77. Cipla's entire theory is predicated on an MDI that *does not have ribs*, and Mr. Anderson utterly failed to consider whether ribs would be suitable given the structure and operation of the '406 Publication's MDI. FOF 77-78. Nor did Mr. Anderson testify that the '406 Publication suffered from any of the problems he suggested ribs could ameliorate. FOF 80. Dr. Lewis *did* consider this issue—he explained how the '406 Publication works, and why its design makes ribs unnecessary and inappropriate. FOF 79, 81-85.

Design engineering principles dictate that POSA would not have added ribs to the MDI of the '406 Publication without a specific reason to do so. FOF 81. To the

contrary, the POSA would have appreciated that *any* change to an MDI risks altering medication delivery, and that even the smallest such changes could result in decades of work to resolve. FOF 81-82. Dr. Lewis testified that the POSA would have had no reason to believe the '406 Publication's MDI suffered from any of the problems Mr. Anderson suggested would generally support inclusion of ribs. FOF 79-81. Mr. Karg further testified that as a design principle, engineers seek to make "minimal changes" because there are always knock-on effects" that "spillover." FOF 81-82.

In particular, the POSA would have appreciated that the '406 Publication's MDI did not need support ribs in order to reduce canister rocking, because it uses a wholly different method of stabilizing the canister. FOF 79. When the canister is depressed, the valve on the bottom (shaped like an upside-down "top hat") drops into a recess in the dose counter and is stabilized by the complementary fit. *Id.* In light of this design, the '406 Publication "doesn't need any more support" from ribs. *Id.*

The POSA also would have anticipated significant *downsides* to adding support ribs to the '406 Publication. FOF 82-85. For one, there was already "a lot of material" in the '406 Publication's inhaler, and the POSA would have wanted to avoid adding yet more internal components. FOF 83. In addition, the POSA would not have "want[ed] to obstruct the movement of that canister which is sitting on the dose counter"—in short, ribs would "get in the way." *Id.* Most importantly, though, the POSA would not have wanted to alter the airflow of the device. FOF 84. Ribs "impede airflow, and they change how the airflow [in an MDI] occurs. . . . So if you can leave them out, as in a

number of products that I worked with, then you leave them out." FOF 84.

Thus, the POSA would have understood that adding a rib to the '406 Publication was "not a good idea" and would disrupt the otherwise "good design" of the '406 Publication. FOF 82, 84 ("If you add that extra rib all you are doing is adding to the downsides of this design poor airflow, restriction of drug delivery."). Mr. Anderson's conclusory testimony that the POSA would have been motivated to "enhance" MDIs by adding ribs addressed none of this nuance. FOF 85. His motivation theory fails.

c. Cipla Failed to Prove that the POSA Would Have Selected the Ribs of the '514 Publication

Cipla's motivation to combine analysis fails for still another reason. Even if the POSA (1) chose to make a dose counter rather than an indicator, (2) chose to locate the counter internally rather than outside the inhaler body, (3) chose not to affix the counter to the canister, (4) viewed the '406 Publication as a suitable starting point, *and* (5) was motivated to add rails to the '406 Publication, Cipla *still* failed to show that the POSA would have selected the ribs *from the '514 Publication* for combination with the MDI of the '406 Publication. Because this is the only theory of invalidity that Cipla ran at trial, that failure also dooms Cipla's case. *WBIP*, 829 F.3d at 1337; FOF 95.

1) Cipla Offered No Reason to Select the Ribs of the '514 Publication

Mr. Anderson identified a number of references disclosing inhaler bodies with ribs. FOF 87. He offered not one word of explanation for why the POSA would have selected the four, equally-spaced ribs *of the '514 Publication*. *Id.* In fact, it was not clear

from Mr. Anderson's testimony that this is what he believes the POSA would have done. *Id.* On cross examination, he suggested the POSA instead could have selected various, balanced numbers of ribs: "It could be three. I would recommend that as a minimum. You can put in six. Why would you put in too many, but three minimum." *Id.* That is far from clear-and-convincing evidence that the POSA would have selected the *four* ribs of the '514 Publication. There is no reason the POSA would have done so,[4] and many reasons why not. FOF 89-95. Cipla does not argue the POSA would have arrived at Teva's invention *unless* the POSA made that unlikely choice. FOF 95.

2) The '514 Publication's Principle of Operation Conflicts with the '406 Publication

Cipla also failed to explain why the POSA would have selected the ribs from the '514 Publication, to the exclusion of all other features, and combined them with a dose counter that rejects the '514 Publication's fundamental teaching. That is fatal to Cipla's case. *See St. Jude Med., LLC v. Snyders Heart Valve LLC*, 977 F.3d 1232, 1242-43 (Fed. Cir. 2020) (no proof of obviousness where challenger failed to explain why POSA would have kept some but not other elements of a reference for combination).

[4] There is no evidence *the POSA* would have selected the ribs of the '514 Publication in *2010*. FOF 88. But it is easy to understand why *Cipla's attorneys* selected the ribs of the '514 Publication in *November 2022*. Cipla sought a reference with a rib located on the "rear of the device." Br. 35; FOF 88. According to Cipla's attorneys: *if* the POSA chose to take that rib out of the '514 Publication, and put it into a *different* inhaler body at (for reasons wholly undisclosed) *precisely the same location it occupied in the '514 Publication*, that rib would lie in the Common Plane. *Id.* No evidence supports this argument, FOF 88, but without a "rear" rib, Cipla would have been left with no argument at all. Cipla's selection of the '514 Publication is pure hindsight, and must be rejected. COL 13, 19.

The '514 Publication discloses a dose counter *affixed* to the medicament canister. FOF 91. As Dr. Lewis explained, the '514 Publication is "all about fixing the dose counter to the canister"—a "great idea" that is the '514 Publication's core teaching and fundamental principle of operation. FOF 91-92. Affixing the counter to the canister comes with substantial advantages—most importantly, it means "you don't have to solve the rocking problem." FOF 92. In the primary embodiment of the '514 Publication, when the patient depresses the canister, the canister/counter assembly moves downward together and the counter strikes a corner of a rib, causing the counter to increment. FOF 91. Thus, the ribs of the '514 Publication work *with* the affixed dose counter to create a functional and accurate device. As of the priority date, *the only marketed MDI with an internal counter utilized this approach. Id.* If the POSA *had* turned to the '514 Publication, the POSA would have "take[n] away the fact that you are going to fix the dose counter to the canister." FOF 93.

Cipla's obviousness theory requires the POSA to disregard that core feature of the '514 Publication, and to focus inexplicably on the fact that multiple figures, when combined, show four equally spaced ribs. FOF 93. Mr. Anderson never grappled with the essence of the '514 Publication—much like he never wrestled with the '406 Publication—and thus he never explained in his trial testimony why the POSA would have ignored the '514 Publication's core teaching (dose counters affixed to canisters), plucked out an isolated component unrelated to that teaching (four ribs), and sought to integrate that component into a different MDI (of the '406 Publication) that is the

antithesis of the '514 Publication's core principle of operation, because its dose counter is moveable relative to the canister. Cipla's theory is just as implausible as expecting a Tesla driver to trade in his electric sedan, buy a diesel truck, and add a sunroof. FOF 94 (Cipla's theory requires the POSA to "completely disregard[] the teachings of the '514 [Publication]."). Because Cipla's farfetched combination would "change the principles under which [a reference] operates," it must be rejected. *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359-60 (Fed. Cir. 2020) ("fundamental differences" between references preclude combination); COL 23. Cipla's theory fails yet again.

d. Cipla Failed to Prove that the POSA Would Have Been Motivated to Combine the '406 and '514 Publications *in a Manner that Led to the Claimed Invention*

Proof of obviousness requires not just that the POSA would have been motivated to combine the references Cipla identified, but that the POSA would have had reason to combine them "in the way the claimed invention does." *ActiveVideo*, 694 F. 3d at 1328. Thus, Cipla must prove by clear-and-convincing evidence not just that the POSA would have been motivated to add the ribs of the '514 Publication to the MDI of the '406 Publication, but also that the POSA would have *aligned* those ribs in a manner that meets the Common Plane Limitation. Cipla never attempted to meet this burden. Nor did Cipla adduce evidence that if the references were so combined, the resulting ribs would have been "arranged to reduce canister rocking," as all claims require. Both failures are fatal to Cipla's invalidity theory.

1) Cipla Failed to Prove the POSA's Motivation to

Align a Rib in the Common Plane

Cipla's evidence that the combination of the '406 and '514 Publications would have met the Common Plane Limitation is driven by hindsight and devoid of analysis. Dr. Lewis explained why the Court should not adopt it.

a) No Evidence Suggests the POSA would Have Selected a Particular Rib Location

First, Cipla offered no evidence whatsoever that *if* the POSA chose to take the ribs from the '514 Publication and splice them into the inhaler of the '406 Publication, that the POSA would have additionally *chosen to arrange* the ribs in any particular way—let alone in a way that meets the Common Plane Limitation. FOF 96. Mr. Anderson did not testify as to any such reason, nor could he have done—the prior art disclosed no connection between ribs and dose counters. FOF 100-103. Certainly, nothing in the art suggested what Teva discovered—namely, that aligning a support rail and dose counter in this manner could improve dose counter accuracy. *Id.*

In his pretrial deposition, Mr. Anderson agreed. He confirmed that "[t]here is no disclosure anywhere in the '406 Publication or the '514 Publication that suggests it is important to put support rails in particular places to prevent canister rocking." FOF 101. That statement should be dispositive of Cipla's entire obviousness theory—it is an honest admission that *nothing* in the prior art suggested combining Cipla's references in a manner that would have led the POSA to Teva's invention, as the record reflects.

At trial, Mr. Anderson attempted to contradict his earlier sworn testimony, but

did not do so in any way helpful to Cipla's cause. Certainly, he did *not* opine that the POSA would have had *reason* to align a support rail with an actuation member and central outlet port when combining the '406 Publication and '514 Publication. FOF 97. Instead, Mr. Anderson casually argued, "Why would you put them in not an important place?" FOF 102. Such musings are not clear-and-convincing evidence of invalidity: Mr. Anderson never once identified *what place* the POSA would have identified as an important place, or *why* the POSA would have come to such a conclusion. *Id.* Instead, Mr. Anderson emphasized that the POSA would have faced a lot of choice in where to place the ribs, and would have needed to choose carefully:

> [T]he places that you put the rails or the ribs, I mean, ultimately you are given quite a lot of choice. And within the actual space that you are talking about, yet you got to choose carefully -- you do have to choose carefully where you put them. And you do have to think about it.

FOF 99. How the POSA would have made a "careful[]" choice, Mr. Anderson never said. FOF 100. Certainly, he never provided a reason for the choice that Cipla's whole obviousness theory depends upon: the choice to align a support rail in a common plane with an actuation member and the central outlet port. FOF 97; COL 18.

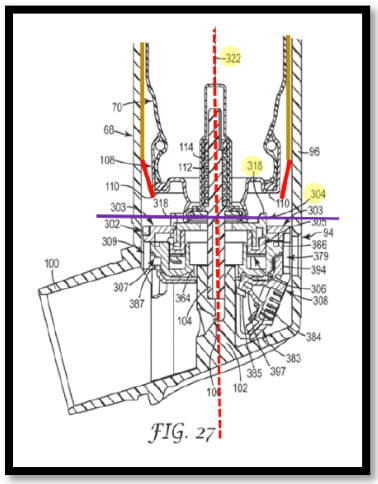
Dr. Lewis's testimony only underscores Cipla's failure of proof. FOF 98. ***First***, Dr. Lewis confirmed that the POSA would have faced myriad options if the POSA had (contrary to his opinion) chosen to add four equally spaced ribs to the '406 Publication:

> Q. . . . [H]ow many ways are there to put four evenly spaced rails in an inhaler body?
>
> A. Well, you can put them pretty much anywhere. So certainly back in that

> period, there were rails being included, but there was no format. Each set of rails would be put into a different place by different inhaler manufacturers if they were included. (Tr. 712:15-20)
>
> * * *
>
> Q. . . . If the POSA took the rails of the '514 publication and put them in an inhaler body … of the '406 publication, would that necessarily result in the common plane?
>
> A. Absolutely not. No. It could be arranged in any order. (Tr. 713:20-24)

Second, Dr. Lewis confirmed that there would have been "no reason at all" to choose, out of the virtually infinite options, an configuration that met the Common Plane Limitation:

> Q. And is there any teaching anywhere in the art that Mr. Anderson has identified or that you've seen to arrange support rails in a particular location relative to components of the dose counter?
>
> A. Absolutely not. As I highlighted, I worked with a number of inhalers and developed inhalers and worked with companies with and without rails. No, there was no format.
>
> Q. And does the prior art ever disclose or suggest to the POSA that there is a reason to arrange rails in order to reduce the rocking of the canister and improve counter accuracy?
>
> A. No. Not at all. Never.
>
> Q. Had anyone in the art even appreciated that rocking was a problem that related to dose counter accuracy?
>
> A. At that point it was -- no. It was unknown.
>
> Q. So in the absence of understanding this problem, is there any reason the POSA would have aligned support rails in a common plane, the actuation member of any dose counter?
>
> A. No. There would be no reason at all.



FOF 103. Mr. Anderson's silence on these points reflects that there is no evidence to dispute them. In the absence of such evidence, Cipla's obviousness theory fails.

b) Mr. Anderson's Testimony Was Irrelevant and Conclusory

According to Cipla, Mr. Anderson testified that if the POSA combined the rails of the '514 Publication with the inhaler body of the '406 Publication, the result would *just so happen* to meet the Common Plane Limitation. That is to no avail.

First, Cipla offers a very generous interpretation of Mr. Anderson's testimony. In reality, Mr. Anderson's explanation of how the combination results in the Common Plane Limitation relies entirely on the attorney-generated image below, which simply *assumes* that if the POSA added a rib to the '406 Publication, the POSA would add it in the same place Cipla's attorneys did. Br. 34; FOF 104-106.

Cipla cites DTX-161 for this image and describes it as "annotated." *Id.* That is an understatement. The yellow highlighting, gold lines, red lines and purple line were all added by Cipla's counsel. FOF 104. Only the black and white portion of the image (Figure 27 of the '406 Publication) reflects the disclosure of the prior art. *Id.* According to Cipla, the red lines represent ribs excised from the '514 Publication and plopped inside of the '406 Publication's MDI, Br. 34—even though they look nothing like the ribs of the '514 Publication. FOF 104. Since those ribs would not fit in the '406

Publication, including a fragment of the ribs was Cipla's only choice. FOF 124.

Second, Cipla argues, the purple line it added to Figure 27 of the '406 Publication shows a Common Plane intersecting a red (imaginary) rib, the center of the central outlet port of the '406 Publication, and an actuation member of the '406 Publication. Mr. Anderson said *something* along those lines:

> If we're looking at a -- the common plane, which is the purple line, that purple line goes through the central outlet port. It goes through the inner wall canister support formation. I'm sorry, the other ribs -- I got that wrong. Apologies. And obviously the actuation member. So in summary, the Claim 1 of the '289 patent would have been obvious over the '406 publication when brought together with the '514 publication.

FOF 106. The above diagram is barely decipherable—it is not clear-and-convincing evidence of anything. In fact, it is not even clear that Cipla's counsel drew a purple line connecting the three things Mr. Anderson says the line connects. But even assuming, *arguendo*, that this is what Mr. Anderson's testimony and Cipla's drawing establish, it is irrelevant. If Cipla's drawing shows a rib in the Common Plane, that is because Cipla chose to put it there—not because *the POSA would have had a reason to put it there*. Obviousness requires clear-and-convincing proof of the latter. *InTouch*, 751 F. 3d at 1352 (rejecting expert's "conclusory references" that POSA "could combine these references, not that they would have been motivated to do so."). Cipla offered no evidence of any such reason; Dr. Lewis confirmed there was none. FOF 104-109.

c) Dr. Lewis Rejected Cipla's Theory

Dr. Lewis did not "all but admit" that combining the inhaler of the '406

Publication with the ribs of the '514 Publication would satisfy the Common Plane Limitation. To the contrary, as Dr. Lewis testified, *if* the POSA were to make that unlikely combination, there are many ways the POSA could have oriented the ribs of the '514 Publication in the inhaler of the '406 Publication, and *no reason* the POSA would have chosen to align the ribs such that one was in the Common Plane. *Supra* § III.B.1.d.1)a); *compare* Br. 36 (suggesting inaccurately that "Dr. Lewis notably did not say the limitation would not be met by the combination") *with* FOF 98, 107. Dr. Lewis did not "sacrifice his credibility" by refusing to agree with Cipla's contrived analysis,[5] and Cipla's effort to cure the failures of its own affirmative case by conjuring admissions Dr. Lewis did not make does not meet Cipla's burden of proof.

Similarly insubstantial is Cipla's passing reference to locating "one of four equally spaced ribs" at the back of the inhaler—an orientation Mr. Anderson never once identified, referenced, or endorsed. Br. 35. The mere fact that one of the ribs in the '514 Publication is located at the rear of the '514 Publication's inhaler does *not* provide a reason for the POSA to locate ribs in an identical manner in the *wholly different inhaler body* of the '406 Publication, which the POSA would have needed to alter in undisclosed ways to accommodate any ribs at all. FOF 108. Mr. Anderson presented a single theory

[5] Cipla faults Dr. Lewis for his consistent testimony, which—while not the answer Cipla sought—plainly reflected his honest belief (*i.e.*, that the POSA would not have combined two references). Br. 36. Cipla's expert, by contrast, testified throughout the trial as though his deposition had not occurred, and routinely offered opinions that directly conflicted with his prior sworn testimony. FOF 195, 199.

of obviousness: that the POSA would have taken the ribs out of the '514 Publication and put them, somehow, into the inhaler body of the '406 Publication. FOF 108. Mr. Anderson *never* testified that, in reverse, the POSA would instead transfer the dose counter of the '406 Publication into the inhaler body—complete with ribs in place—of the '514 Publication. FOF 108. Cipla has no testimony—from its own expert, or otherwise—to support this belated, happenstance theory of obviousness. FOF 108.

2) Cipla Failed to Prove that the Rails Would Be Arranged to Reduce Canister Rocking

Cipla failed to offer any analysis whatsoever regarding whether the ribs of the '514 Publication—after being imported into the '406 Publication and any necessary size adjustments made—would have been "arranged to reduce canister rocking," as every Asserted Claim requires. FOF 110-111. Mr. Anderson offered no testimony in support of such an inference, FOF 111, leaving Cipla to rely only on attorney argument.

First, Cipla cites a statement in the '514 Publication that ribs "may be positioned within the chamber of the cylindrical portion to aid in locating and supporting the container in the correct position." Br. 32 (citing DTX-165 at 14:18-19). That reflects ribs *as they are designed and used in the '514 Publication*. No evidence suggests that if those ribs were excised and altered to fit into a different inhaler—which uses a different mechanism to prevent canister rocking, FOF 112—that they would perform the same function. Cipla identifies no testimony to support its unfounded inference.

Second, Cipla relies, incredibly, on attorney colloquy during the course of its

objections to Dr. Lewis's infringement testimony. Br. 42. Attorney argument regarding Rule 26 disclosures is not *evidence*—it cannot satisfy Cipla's burden of proof. Regardless, Cipla misrepresents Teva's infringement position. Teva did not argue that *any* feature extending outwardly from the inner wall of *any* inhaler body is necessarily arranged to reduce canister rocking. Instead, Teva argued that the "front" rib as arranged in *Cipla's* device reduces canister rocking—an observable fact. FOF 114. That is wholly irrelevant to the question of whether a different rib with a different shape in a different, imaginary inhaler would *also* limit the canister's freedom of movement.

Indeed, if one accepts Cipla's "annotated" drawing above as the outcome of a combination of the '406 and '514 Publications, nothing suggests the small, flap-shaped ribs Cipla depicts would or could reduce canister rocking—certainly, they do not "go to the top of the inhaler body" as Cipla suggests. Br. 42. Holding Cipla to its burden to prove that the ribs resulting from its proposed combination would be "arranged to reduce canister rocking" is faithful to the "axiom[] that claims are construed the same way for both invalidity and infringement." *Source Search Techs., LLC v. LendingTree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009). Cipla failed to meet that burden.

2. Cipla Failed to Prove the POSA Would Reasonably Have Expected Success in Combining the Asserted References

For each of the independent reasons detailed above, Cipla failed to prove by clear-and-convincing evidence that the POSA would have been motivated to combine the '406 and '514 Publications in a manner that would have led to the claimed

inventions. The Court need proceed no further, because each of those reasons alone is sufficient to doom Cipla's obviousness case. Nevertheless, Cipla's theory fails for another, equally important reason: Cipla failed to show that the POSA reasonably would have expected success in combining the '406 and '514 Publications.

Expectation of success is a distinct and critical element of any obviousness challenge; failure to prove it is fatal. *See, e.g.*, *Samsung Elecs. v. Elm 3DS Innovations*, 925 F. 3d 1373, 1383-84 (Fed. Cir. 2019) (declining to consider motivation where challenger failed to show reasonable expectation of success). Here, Cipla made no more than a cursory effort to satisfy its obligation. Perhaps in an effort to elide this failure, Cipla conflates the expectation analysis into a section heading with its motivation argument (*see* Br. 36), but offers no analysis of this separate point. This failure is dispositive, especially given the ample proof that the POSA would *not* have expected the combination of the '406 and '514 Publications to be successful.

a. Cipla Failed to Address Expectation of Success

Cipla's invalidity brief rests its entire expectation of success argument on two lines of testimony from Mr. Anderson and one statement from the '406 Publication. Br. 36. This is legally insufficient to meet Cipla's clear-and-convincing burden.

Cipla relies on the testimony below from Mr. Anderson's direct examination:

> Q. Would a POSA be motivated, in view of what you just told me, to combine the '406 publication with a '514 publication disclosing these ribs with expectation of success?
>
> A. Yeah. They would definitely be motivated to combine the '406 with

the '514 and a high expectation of success.

Br. 36 (citing FOF ¶¶ 151-55). That is it. Full stop. Cipla relies on *no other testimony* from Mr. Anderson in support of any statements in its brief or Findings of Fact related to expectation of success for claim 1. Br. §§ VI.A.3 (citing Cipla FOF ¶¶ 146-166), VI.C.3 (citing Cipla FOF ¶¶ 192-193, 221). In fact, Cipla mentions expectation of success exactly twice in its findings of fact with respect to claim 1 of the '289 patent—first, in paragraph 153, citing the exchange above, and second in paragraph 166 cross referencing the same testimony. The cited testimony no more than an unadorned conclusion, and is woefully insufficient to support a finding of obviousness. *ActiveVideo*, 694 F. 3d at 1328. The conclusion also fails to grapple with any of the reasons the POSA would have feared that the combination of the '406 and '514 Publications would *not* have worked. FOF 116-110; *supra* §§ III.B.1.b-III.B.1.d.

That Cipla cited no trial evidence to carry its burden is not for failure to search the record; there was simply nothing to find. Aside from similarly conclusory statements sprinkled throughout his direct, FOF 117, Mr. Anderson was asked precisely once to explain the rationale for his reasonable expectation of success opinion. Tr. 577:13-16 ("Now, I want to ask you why is your opinion that a POSA would have had expectation of success when combining the '406 or the '514 regarding your obviousness opinion on Claim 1 of the '289 patent?"). His response did not address expectation of success in the slightest. Instead, Mr. Anderson offered wholly inapposite testimony as to his belief that Cipla's annotation of figure 27 of the '406 Publication (DXT-161)

shows a purple line connecting a red (added) rib, the center of the central outlet port, and an actuation member. Tr. 577:17-578:9. Even Cipla acknowledges that this is all Mr. Anderson said, because Cipla relies on this testimony only in Section VI.A.3 of its brief (arguing that the combination would lead to a rib in the common plane), not in Section VI.A.2 (discussing expectation of success in its title, if nowhere else).

At trial, Mr. Anderson *never* explained why—*if* the POSA *had* chosen to add the ribs of the '514 Publication to the MDI of the '406 Publication—the POSA would have expected the device of the '406 Publication to accommodate those ribs, whether and how the MDI or ribs would need to be adjusted, whether such modifications were feasible, and whether the resulting device still would have dispensed medicine and counted accurately. *Id.* The law of obviousness demanded that analysis. *Samsung*, 925 F.3d 1381 (no expectation of success where expert failed to explain how one reference would be changed to accommodate combination with another).

In a last-ditch effort to save its case, Cipla points to the '406 Publication itself, which states that its dose counter is designed to "fit compactly within commercially available actuator housing profiles so that it is not necessary to change the external configuration of those actuator housings to accommodate the inventive dose counter therein." Br. 36 (citing DTX-161 at [00105]). Mr. Anderson never relied on this statement in reaching his conclusion of obviousness, and for good reason: It has nothing to do with Cipla's theory. Cipla's argument is that the POSA would have *added ribs to the inhaler body* of the '406 Publication, not that the POSA would have taken the

dose counter out of the '406 Publication and put it into a different inhaler body. FOF 119. There was no testimony at trial as to how the POSA would have interpreted this phrase, which does not suggest that the relevant "commercially available" inhaler bodies have ribs, nor does it suggest that changes to *internal* features (like ribs) also could be avoided. FOF 119. In light of Dr. Lewis's testimony as to why the POSA would *not* have expected the ribs of the '514 Publication to work with the inhaler and dose counter of the '406 Publication, this single line cannot carry Cipla's burden.

b. Dr. Lewis Explained Why the POSA Would Not Have Expected Cipla's Combination to Be Successful

Dr. Lewis explained multiple reasons why the POSA would *not* have expected success in adding the ribs of the '514 Publication to the MDI of the '406 Publication.

First and foremost, making an MDI with an integrated dose counter is no small feat. MDIs with dose counters are "very complex" and must be carefully designed, because they must be robust to the variable use of tens of millions of people who will use them in ways their designers cannot even imagine. FOF 121. MDIs are designed to look "very simple" but they are "actually extremely complex." *Id.*

As a result of this complexity, inhalers and dose counters cannot simply be mixed and matched—as the POSA would have appreciated, swapping parts from one system into another is not predictable, and "[m]ost of the time this is not going to work." Tr. 145:5-14; FOF 122. The components of a system are designed to work together and changing one component can alter the function of others. FOF 122.

MDI systems were especially challenging to tweak when they had a counter located inside the inhaler body, as in the case of the '406 Publication. FOF 123-124. The most important feature of an MDI is that it deliver medicine successfully—risking interference in delivery of the medicine is a "deal-breaker." FOF 123. But that is precisely what happens when features are added to the inside of an inhaler body:

> You start putting anything inside, you are going to change the flow path. Once you put a patient's mouth in front of this, there is going to be backflow. Anything you put upstream, it is going to have a big change in how, essentially, the medicine reaches the lungs.

Tr. 685:20-24. Mr. Anderson did not dispute any of these opinions, nor account for any of these concerns when he testified generally as to motivation. FOF 124. Dr. Lewis, in contrast, tailored his analysis to the specific references at issue. FOF 124.

In particular, Dr. Lewis explained that the rails from the '514 Publication were "not going to fit" into the device of the '406 Publication. FOF 124. While it is true that references need not be physically combinable in order for combination of their features to have been obvious, Br. 43, Cipla failed to produce evidence at trial of *how* the '406 Publication would be modified to accommodate ribs, and *why* the POSA would have expected that further-modified combination to work. FOF 124; *Samsung*, 925 F. 3d at 1381 (obviousness theory failed where challenger failed to explain how one reference would be altered to accommodate combination). Dr. Lewis, on the other hand, explained why adding ribs to the '406 Publication would not have worked, even if they were sized appropriately: one would not know whether or how the POSA

would have been able to modify the device to accommodate a rib, including because the POSA would have expected that ribs would have "obstruct[ed] the movement of th[e] canister," and "add[ed] to the downsides of [the '406 Publication's] design poor airflow, restriction of drug delivery." Tr. 794:21-23. As Dr. Lewis explained, "none of this is going to work." Tr. 796:1. The POSA would have expected the same.

C. The Dependent Claims Would Not Have Been Obvious

Each of claims 2, 4, 6, and 7 depend from Claim 1, and thus would not have been obvious for all the reasons explained above. *Supra* Section III.B. Further, Cipla failed to prove obviousness of each dependent claim for the additional reasons below.

1. Claim 2 Would Not Have Been Obvious

Claim 2 additionally requires that the "medicament canister is moveable relative to the dose counter." JTX-003. Dr. Lewis explained that the POSA in 2010 who decided to make an internal dose counter would have chosen to *affix* the counter to the canister. *Supra* p. 9. That configuration had many advantages when compared with a moveable option, which was "very difficult" to design. FOF 68-73, 126-132. Indeed, the only marketed MDI with an internal dose counter at the time of Teva's invention took the *affix* approach, and the POSA would have done the same. FOF 70. Furthermore, if the POSA had relied on the '514 Publication—as Cipla's theory requires—the POSA would have adhered to its core principle of operation, *supra* Section III.B.1.c.2), and attached the dose counter to the canister, FOF 69-73. Cipla cannot prove obviousness of claim 2 by clear-and-convincing evidence when one of

the only two references it relies upon instructed the POSA to take a diametrically opposed approach. *Adidas*, 963 F.3d at 1359-60.

Mr. Anderson blithely ignored this complication, Tr. 578:12-24, and Cipla's new rejoinder—that Teva's *infringement* allegations somehow evidence obviousness, Br. 40—reeks of hindsight. Choices Cipla made decades *after* Teva's invention provide *no* evidence of the choices the POSA *would have made in 2010*. As Dr. Lewis explained, *if* the POSA *had* plucked the '406 and '514 Publications from the sea of prior art, the POSA would not have combined them in a way that violates the core principle of the '514 Publication. FOF 91-95. Cipla cannot establish invalidity by clear-and-convincing evidence by failing even to acknowledge this concern.

2. Claims 4, 6 and 7 Would Not Have Been Obvious

Each of claims 4, 6, and 7 requires that the inner wall canister support formation in the Common Plane extends longitudinally along the inside wall of the inhaler body. Cipla asserts that its proposed combination of the '406 and '514 would meet this limitation because the ribs shown in the figures of the '514 Publication are such support rails. Br. 40. The unrebutted evidence shows, however, that the support rails as shown in the '514 Publication would not have fit into the '406 Publication's MDI, FOF 124, 135, and Mr. Anderson offered no testimony to explain how they would be adjusted to become compatible, FOF 135. In fact, in the annotated version of Figure 27 that Cipla asserts reflects the result of its proposed combination, the ribs do *not* extend longitudinally—they are flaps at the bottom of the inhaler body. FOF 112. Cipla failed

to prove dependent claims 4, 6, and 7 obvious for this additional reason.

IV. The Asserted Claims of the '587 Patent Would Not Have Been Obvious

The Asserted Claims of the '587 Patent contain *every* limitation of the Asserted Claims of the '289 Patent, and are thus not obvious for every reason explained above. But, the Asserted Claims of the '587 Patent also contain *additional* limitations. The unrebutted testimony shows that these limitations make the claims of the '587 Patent narrower than the claims of the '289 Patent—indeed, Cipla relied on this narrower scope as a second basis for noninfringement. When it came to validity, however, Cipla dismissed these additional limitations as meaningless, and did not even attempt to show that they were taught by the prior art or would have been obvious. The law is clear: claims must be interpreted the same way for infringement as validity. *Source Search*, 588 F.3d 1075. These limitations have meaning, Cipla's product satisfies those limitations (Teva Op. Br.), but Cipla failed to address them in its obviousness analysis. Cipla thus failed to prove the '587 Patent invalid by clear and convincing evidence.

A. Claims 1 and 12 of the '587 Patent Contain Additional Limitations

The independent claims of the '587 Patent contain language that claim 1 of the '289 Patent does not. Specifically, claim 1 of the '587 Patent requires that an inner wall canister support formation be arranged "*such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister*

relative to the main body of the inhaler." FOF 141. Claim 12 is similar.[6] FOF 142. These "extra" limitations in the '587 Patent are referred to as the "Rocking Limitations."

As Dr. Lewis explained, this additional language (the Rocking Limitation) further limits the structure of inhalers that infringe the '587 Patent: not every rib that meets the Common Plane Limitation *also* "protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler." FOF 145. That depends on the rib's size, shape, and location. FOF 145.

Cipla certainly thought the Rocking Limitation had meaning when it put on its noninfringement case. Mr. Anderson testified as follows:

> Q. Are there any additional limitations in '587 patent, Claim 1 that, in your opinion, aren't met by Cipla's ANDA device?
>
> A. The rocking.
>
> Q. Mr. Anderson, can you be a little more specific in terms of what limitation -- in the '587 patent, Claim 1, what additional limitations ae missing in Cipla's ANDA product?
>
> A. Yeah, such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

FOF 145. This is consistent with Cipla's approach to claim construction, where Cipla *agreed on a meaning* for the Rocking Limitation of claim 1, instead of asserting it was meaningless. D.E. 102 at 5 (agreed construction: "guards against unwanted actuation

[6] The differences between the Rocking Limitation of claim 1 and that of claim 12 are meaningful, FOF 143-144, but not dispositive here—Cipla argues (incorrectly) that both are equally meaningless, and fails to offer a prior art case against either one.

by reducing rocking of the medicament canister relative to the main body of the inhaler that would otherwise be of a magnitude sufficient to move the dose counter's actuator enough to cause unwanted incrementing (or decrementing) of the dose counter").

Cipla changes its tune dramatically when briefing obviousness. Now, it asserts, the Rocking Limitations "add[] nothing structural, and therefore, no patentable weight." Br. 48. Cipla is wrong for several reasons.

First, the law does not countenance Cipla's "heads I win, tails you lose" approach. Rather, "it is axiomatic that claims are construed the same way for both invalidity and infringement." *Source Search*, 588 F.3d at 1075 (collecting cases). Cipla argued the limitation was meaningful during its infringement case—that is the correct understanding of the claim, it is embraced by the parties agreed upon claim construction for claim 1, and it must be applied to the validity analysis as well.

Second, Dr. Lewis testified without contradiction from Mr. Anderson that the Rocking Limitations do, in fact, impose structural limitations on the claim:

> Q. And the mere fact, the fact that you have an inner wall canister support formation in a common plane, does that mean that that inner wall canister support formation necessarily protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the dose counter?
>
> A. It doesn't necessarily protect.
>
> Q. Does it depend on the configuration?
>
> A. Yes. Absolutely, yes.

* * *

> Q. . . . Does the extra language, the [Rocking Limitation] in Claim 1 of the '587 patent, does that impose an additional limitation on the structure of the inhaler that's not in the '289 patent?
>
> A. Yes, it does.

FOF 145. Thus, the Rocking Limitations do not merely recite the purpose of the Common Plane Limitation, they impose *structural* limitations on the inhalers that fall within the scope of the claim.

Cipla's cited cases, Br. 48, are thus inapposite. *Catalina Marketing* addressed claim language that related only to purpose and did not limit structure as the Rocking Limitations of the '587 Patent do. Br. 48 (citing 289 F.3d 801, 809 (Fed. Cir. 2002)). Moreover, the disputed language in *Catalina* was in a claim *preamble*—a portion of the claim that often recites purpose, is frequently nonlimiting, and is subject to special analysis not applicable here (because the Rocking Limitations are not in the preamble.

Cipla's reliance on *Schrieber* fares no better. The Rocking Limitations do not recite a "new intended use for an old product"—they recite additional features of a new product in functional terms. *Schrieber* explicitly endorses this approach. *Id.* at 1478 ("A patent applicant is free to recite features of an apparatus either structurally or functionally."). The claim in *Schrieber* dealt with a popcorn dispenser—it required, in part, a top with a uniform taper, "such as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted on the container." *Id.* The Federal Circuit acknowledged that such functional language can impose meaningful limitations on

apparatus structure, and proceeded to evaluate whether the prior art disclosed this limitation. *Id.* at 1478. The Court ultimately found the claim anticipated ***after evaluating whether the prior art disclosed the claimed limitation***. *Id.* The same analysis is required here, but a different result follows, because Cipla has not identified prior art that discloses or suggests the Rocking Limitations.

Finally, Cipla's reliance on the examiner's cursory statement during prosecution that the Rocking Limitations recite only "purpose" is insufficient. The examiner's statement was made in the context of a "double patenting" concern that the term of the '587 Patent might extend beyond that of the '289 Patent. FOF 147. Teva addressed this issue by filing a "terminal disclaimer" that ensured the two patents would expire on the same date, without addressing the merits of the examiner's argument. *Id.*

B. Cipla Provided No Evidence of Obviousness for the '587 Patent

Given the Rocking Limitations in the '587 Patent, there can be no meaningful dispute that Cipla failed to conduct a proper obviousness analysis for the Asserted Claims of the '587 Patent. Mr. Anderson's entire opinion was as follows:

> Q. Can you please explain your opinion that Claim 1 of the '587 patent would have been obvious in view of the '406 in combination with the '514?
>
> A. Yeah. Because it's -- when you have a look at these, obviously the claims are very similar, apart from there is in red here, there is an additional part where it actually says such that the inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler. And that's kind of giving a little bit more purpose, yet, to the claim limitation.

> Q. So in view of that, is it your opinion that Claim 1 of the '587 patent would have been obvious in view of the '406 publication, the '514 for the same reasons you described for Claim 1 in the '289 patent?
>
> A. Yes. Definitely. Just to confirm, the '289 patent, Claim 1 versus the '587 Claim 1, they are obvious, you know, for the same reasons.

Tr. 583:3-21; *id.* at 584:9-21 (similar with respect to claim 12). At no point did Mr. Anderson identify *any* disclosure of the Rocking Limitation in the prior art, nor did he explain how the combination of the '406 and '514 Publications would have satisfied the Rocking Limitation. Cipla's post-trial brief fares no better—it notes that the ribs of the '514 Publication extend to the top of the wall of the inhaler body, and asserts that they would necessarily reduce rocking, and thereby "satisfy the additional purpose language" of the '587 Patent. Br. 48. This is both wrong and irrelevant. There is no basis to assume that just because a rib reduces rocking it protects against unwanted dose counter errors—Dr. Lewis testified to the contrary without contradiction. FOF 145. Moreover, the question is not what the '514 Publication's ribs do in the '514 Publication, but what those ribs would do if imported into the inhaler of the '406 Publication. No evidence supports the conclusion that the ribs in this modified device would extend to the top of the inhaler—Cipla's annotated Figure 27 suggests the contrary.

The bottom line is that Cipla made no effort to compare the Asserted Claims of the '587 Patent to the prior art. The record does not support a conclusion of invalidity. Claims 2, 4, and 6-7 are additionally nonobvious for the reasons of Section III.C.

V. The Asserted Claim of the '808 Patent Would Not Have Been Obvious.

At trial, Cipla asserted two obviousness theories on Asserted Claim 28 of the '808 Patent, based on the '406 and '552 Publications, respectively. Neither is a winner.

Cipla's theory based on the '552 Publication (Br. 16-29) has already been rejected by a scientifically trained, three-judge panel of the Patent Trial and Appeal Board ("PTAB").[7] During prosecution of the '808 Patent, the examiner considered whether claim 28 would have been obvious based on the '950 Publication—a reference indistinguishable from the '552 Publication that Cipla relies on. FOF 186-188. The PTAB, considering the issue on appeal from the examiner, held that just because the '950 Publication's figures resembled those of the '808 Patent, the '950 Publication did not render the '808 Patent obvious. FOF 189.

Despite acknowledging the PTAB's ruling, Mr. Anderson advanced obviousness theories in his reports based on both the '950 and '552 Publications, where he admitted that both references "disclose the same configuration." FOF 188. At trial, Cipla tried to bury the PTAB's decision by having Mr. Anderson refer only to the '552 Publication during direct examination. But after the Court overruled Cipla's objections, he was forced to admit to his prior opinions equating the '950 Publication and the '552 Publication. FOF 188; Tr. 586:11-587:15 (Anderson). Cipla failed to hide the fact that the PTAB long ago rejected the same theory of obviousness it presses on this Court; the PTAB's decision stands as highly "persuasive authority" as to the '808 Patent's

[7] By statute, the PTAB's "administrative patent judges shall be persons of competent legal knowledge and scientific ability." 35 U.S.C. § 6.

validity. *Worlds, Inc. v. Activision Blizzard, Inc.*, 537 F. Supp. 3d 157, 162 (D. Mass. 2021).

Even taking Cipla's trial arguments in isolation, however, Cipla fails to prove that claim 28 would have been obvious over either the '406 or '552 Publication. Cipla failed to adduce *any* prior art evidence establishing the obviousness of the crucial limitation—a "regulator" which provides a "resistance force" of "greater than 0.3 N." The reason is readily apparent. No such evidence, much less clear-and-convincing evidence, exists. Instead, Cipla and Mr. Anderson were forced to argue simply that the '406 and '552 Publication's drawings depicted devices that were the "same as" Cipla's or Teva's products. Cipla's "same as" strategy does not answer the relevant question; neither the '406 Publication nor the '552 Publication disclose *any* information about the relevant force, much less specifically that it must be greater than 0.3 N.

Worse still, what little analysis Mr. Anderson testified to about the claimed resistance force relied entirely on the explanation provided in the '808 Patent itself about how the inventors arrived at that specific value. That circular reasoning is the epitome of hindsight, and is foreclosed by Federal Circuit precedent: "The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the [POSA] would have followed, as evidenced by the pertinent prior art." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012). That warning is especially salient here, where two inventors testified at trial that Teva itself did not appreciate the problem until late in their efforts, and long after Cipla's prior art references were published.

A. Cipla Failed to Prove the POSA Would Have Selected the '406 and '552 Publication

As a threshold matter, Cipla fails to offer any reason why the POSA would have selected the '406 or '552 Publications for modification. *See WBIP*, 829 F.3d at 1337; Tr. 692:4-15 (Lewis). Cipla's only excuse (offered in connection with the '289 and '587 Patents and addressed only to the '406 Publication, Br. 42-43) misreads the legal principle that the POSA is "presumed" to know the prior art. That a POSA would have been aware of a reference does not establish a POSA "would have plucked" it "out of the sea of prior art" for modification. *Supra* Section III.B.1.a; *WBIP*, 829 F.3d at 1337. Under Federal Circuit precedent, that forecloses Cipla's obviousness defenses. *Id.* Should the Court proceed further, Cipla's theories fail for yet additional reasons.

B. Cipla Failed to Prove Claim 28 Would Have Been Obvious Over the '406 Publication

1. Cipla Cannot Overcome a Failure of Proof

Claim 28 requires a regulator with a "resistance force" of "greater than 0.3 N." Shockingly, Mr. Anderson never testified that a POSA would have arrived at a resistance force of "greater than 0.3 N" in declaring the claim invalid. FOF 160; Tr. 714:19-715:14 (Lewis), 544:13-605:12 (Anderson). Dr. Lewis testified without contradiction that the '406 Publication fails to disclose any of the information needed to determine whether its spring exerts a "resistance force" of "greater than 0.3 N," including the "material the spring is made out of," "the size of the spring" and the "scale of the relative components." FOF 161-162; Tr. 713:25-715:17 (Lewis).

Cipla attempts to bridge this evidentiary gap by citing (1) Dr. Lewis's testimony that 0.3 N is "a very small number"; and (2) attorney argument that "the force caused by dropping an inhaler" "approaches 0.3 N". Br. 15. Both efforts fall well short.

First, whether or not 0.3 N is a "very small number" is irrelevant to obviousness. *See* FOF 164, 169. To prove obviousness, Cipla must not only prove that a POSA would have believed it "possible" to increase the resistance force beyond 0.3 N, but also "on balance, desirable." *Impax Labs.*, 893 F.3d at 1381; *Winner*, 202 F.3d at 1349. To the contrary, the POSA would *not* have chosen a resistance force of greater than 0.3 N—because increasing the resistance force would add to the "compression to the energy that the patient is going to need to push." FOF 164; Tr. 728:5-13 (Lewis).

Cipla attempts to distract from its own expert's fatally deficient testimony by pointing the finger at Dr. Lewis, arguing that he "lacks credibility" because he testified that actuating Cipla's inhaler requires a force much greater than 0.3 N. Br. 15-16. Dr. Lewis in fact testified that it was difficult for him to maintain the actuation force for the length of a single question, Tr. 403:4-11—if anything, Dr. Lewis's testimony suggests it would be ill advised to require yet *more* force to be applied. Regardless, it is Cipla, not Teva who bears the burden of proof on obviousness—Dr. Lewis could have said nothing, and Cipla's evidence would still have been insufficient.

Nevertheless, Dr. Lewis's testimony is amply corroborated by the inventors' testimony that the problem they sought to solve—unwanted movement of the counter display—was itself unexpected, a fact the Federal Circuit has recognized indicative of

nonobviousness. *See, e.g.*, *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013) ("[A]n invention can often be the recognition of a problem itself.").

Declan Walsh, the '808 Patent's lead inventor, testified that the inventors found, in the middle of development, that "the counter display wasn't maintaining accuracy" "because it had the ability to move back and forth of its own accord." FOF 165; Tr. 85:22-90:5, 71:6-72:10 (Walsh). Before choosing to implement the claimed "regulator" with its specific resistance force, the inventors considered at least "six" possible alternatives. *See* FOF 166; Tr. 86:23-90:5 (Walsh); PTX-247 (Brainstorm).

Mr. Jeffrey Karg, an inventor who Teva hired specifically to solve problems that its own engineering team could not, FOF 165; likewise testified that Teva discovered the problem with the counter display during "very late stage testing," FOF 165. Consistent with Dr. Lewis's testimony, and contrary to Cipla's argument, Mr. Karg testified that he had "concerns that increasing the resistance force" would prevent the device from working; because of how the "regulator" interacted with other small, "fragile" components, the inventors "had to find a very fine balance between protecting all the small parts so that they wouldn't break, yet still constrain the rotation enough so that the counter display could not freely rotate." FOF 168; Tr. 636:25-637:13.

Both inventors directly rebutted Cipla's assertions that "small" is tantamount to obvious. As Mr. Walsh explained, the part of the dose counter that contains the regulator is "a quarter of a size of a matchbox" and has "over 100 dimensions." FOF 169. Mr. Karg explained that just developing a preliminary understanding of the

relevant part interactions and "knock on effects" required running "thousands and thousands" of mathematical models using cutting-edge software. *See* FOF 170; Tr. 632:9-25; PTX-223 (CETOL Model). Both testified that the project was one of the most "complex" of their careers. Tr. 96:14-97:17 (Walsh); 637:17-638:9 (Karg).

Second, Cipla's attorney calculations are even more easily disposed. Whatever these calculations are, they are not evidence. *See Invitrogen Corp. v. Clontech Labs.*, Inc., 429 F.3d 1052, 1068 (Fed. Cir. 2005) ("Unsubstantiated attorney argument . . . is no substitute for competent, substantiated expert testimony."). Regardless, Cipla argues the drop force caused by a typical inhaler only amounts to "a force of 0.24 N"—*less* than the claimed 0.3 N. Cipla offers no reason why the POSA would aim higher.

2. Cipla's "Same As" Argument Fails as a Matter of Law

Lacking actual evidence, Cipla turns to more attorney argument. Cipla asserts that the '406 Publication and Cipla's product "share the same mechanism of action and structural features"; so if Cipla infringes, the claimed invention must have been obvious.

As a legal matter, Cipla's assertion that its "dose-counter is practicing the '406 Publication" is not a cognizable invalidity defense. Br. 12. "[I]nfringers are not free to flout the requirement of proving invalidity by clear and convincing evidence by asserting a 'practicing prior art' defense to literal infringement under the less stringent preponderance of the evidence standard." *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365-69 (Fed. Cir. 2002).

Regardless, as a factual matter, Cipla's "same as" argument begs the question of

whether the '406 Publication's MDI and Cipla's product are, in fact, the same —namely, whether the '406 Publication's leaf spring acts as a "regulator" with a "resistance force" of "greater than 0.3 N." On that point, Cipla cites Mr. Anderson's conclusory testimony that Cipla's product has "every single component" that the '406 Publication discloses and that those components are the "same." Br. 11-12. But neither Cipla nor Mr. Anderson identify any disclosure in the '406 Publication regarding how much force its spring exerts, much less that it exerts the *same* force as Cipla's. FOF 162, 173 ('406 Publication does not disclose force of spring or information needed to determine it).

Instead, Cipla and Mr. Anderson cite Dr. Lewis's *infringement testing* of Cipla's device. *See* Br. 12. That does not answer the relevant question. To establish that the '406 Publication and Cipla's product are the same, Cipla needed to prove that their springs exert the same force. Dr. Lewis's testing of Cipla's product obviously does not establish the force of the spring in the '406 Publication. FOF 174.

Cipla criticizes Dr. Lewis's opinions regarding differences between the '406 Publication and Cipla's product, alleging he gave contradictory testimony that the two were "similar." Br. 12. That is not what Dr. Lewis said (he merely acknowledged "similarities"), nor is it inconsistent. FOF 176. "[S]imilarities" do not preclude differences, and Dr. Lewis elsewhere made clear Cipla's device and the '406 Publication were "very different." FOF 176.

3. Cipla's "Routine Optimization" Theory Is Hindsight

Cipla also argues that the claimed "resistance force" of "greater than 0.3 N"

would have been obvious as a matter of "routine experimentation." Here too, Cipla's arguments fail. First, as the trial record reflects, Mr. Anderson never offered any opinion that a POSA would have arrived at the claimed "resistance force" *based on the '406 Publication*. *See* FOF 177. The testimony Cipla cites (Br. 14 (quoting Tr. 557:12-22)) was not directed to the '406 Publication—it concerned the '552 Publication. The difference matters. Obviousness must be based on a "specific combination of prior art elements." *ActiveVideo*, 694 F.3d at 1328. Mr. Anderson's failure is dispositive.

Second, even the testimony that Mr. Anderson did give *relied entirely on guidance in the '808 Patent's own specification. See* FOF 177. Mr. Anderson did not deny that approach, which he did not understand to be legally verboten:

> Q. Why did you decide to rely on the specification of the patent?
>
> A. Because it guides you. It informs you, and some of it is experimental, but some of it is very, very well defined. And they actually provide you charts showing the tolerances that they then worked to, and they give you nominals as well to work from.

Tr. 594:8-14. Of course, the law expressly forbids Mr. Anderson's reliance on the teachings of the challenged patent. Under 35 U.S.C. § 103(a), nonobviousness "shall not be negatived by the manner in which the invention was made." Mr. Anderson's reliance on the inventor's own path to invention is not "a conclusion of obviousness; that is hindsight." *Otsuka Pharm.*, 678 F.3d at 1296. It fails as a matter of law.

C. Cipla Failed to Prove Claim 28 Would Have Been Obvious Over the '552 Publication

Cipla's alternative theory, that the '808 Patent would have been obvious over

another Teva patent application, the '552 Publication, breaks no new ground and has been effectively rejected by the PTAB. Like the '406 Publication, the '552 Publication fails to disclose a "regulator" that provides a "resistance force" of "greater than 0.3 N."

1. Cipla Again Cannot Overcome a Failure of Proof

Again, Dr. Lewis testified without contradiction that the '552 Publication does not disclose any "numerical resistance force" or even "what forces would be required." FOF 182, Tr. 727:10-728:15 (Lewis). Again, Dr. Lewis testified (contradicted only by Cipla's attorneys, *supra* § V.B.1) that increasing the resistance force would have been undesirable because it would increase the "energy that the patient is going to need to push." FOF 182, Tr. 728:5-13 (Lewis). And again, the inventors' testimony established that not even they were aware of the problem the "regulator" solved until late in development—much less, the specific "resistance force" needed to solve it. FOF 182.

2. Cipla's "Routine Optimization" Argument Fails Again

None of Cipla's arguments address its fundamental failure of proof. Cipla repeats the same "routine optimization" argument that it applies to the '406 Publication. *See* Br. 23-24. But as explained above, neither Cipla nor Mr. Anderson offer any evidence, based on the *prior art*, that a POSA would have arrived at a "resistance force" of "greater than 0.3 N" or any other figure. *See supra* § V.B.3. Instead, Mr. Anderson relied impermissibly on the *'808 Patent's explanation* of how *the inventors* arrived at the claimed resistance force. FOF 177. The law forecloses Cipla from using the inventor's description of their inventive path to invalidate their patent. *Supra* § V.B.3.

Cipla also repeats its argument that inhalers are "commonly subjected to forces of greater than 0.3 N." Br. 23. Again, that does not establish that the POSA would have desired to *increase* the force needed to use the inhaler. The only record evidence—Dr. Lewis's and Mr. Karg's testimony—established that the POSA would have avoided doing so, because it would have made the inhaler harder for patients to use and interfered with other "fragile" parts in the device. FOF 164, 168; *supra* § V.B.1.

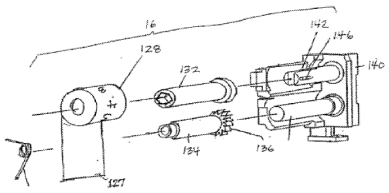
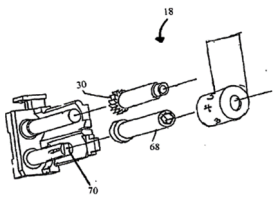
Finally, Cipla asserts that the '552 Publication must disclose a "resistance force" of "greater than 0.3 N" because Dr. Lewis was able to testify that Teva's Qvar® and ProAir® devices satisfied that requirement without testing them. *See* Br. 24. Cipla suggests that, given this testimony, a conclusion of nonobviousness would mean that "claim 28 is invalid under 35 U.S.C. § 112." *Id.* Cipla's argument is unclear, but it is wrong. Dr. Lewis had access to Teva's inventor testimony explaining the regulator in Qvar® and ProAir®, the '406 Publication was a paper drawing of a nonexistent device, FOF 185. It is not surprising Dr. Lewis could reach conclusions about one but not the other.[8] In any event, there is "no tension" in a conclusion that a claim is valid under § 103 and § 112. *Allergan, Inc. v. Sandoz Inc.*, 769 F.3d 1293, 1310 (Fed. Cir. 2015).

3. Cipla's Remaining Arguments Re-Litigate Issues the PTAB Deemed Meritless

[8] Cipla's premise is wrong, but so is its conclusion. If Dr. Lewis lacked sufficient evidence to conclude that the regulators in Qvar® and ProAir® meet claim 28 (and he did not), that would affect only his conclusion of nexus for purposes of objective indicia—not whether the '406 Publication discloses a regulator of claim 28.

Cipla is not the first to fail in proving that the '808 Patent would have been obvious based on this theory. During prosecution of the '808 Patent, the PTAB found that the '950 Publication, which Cipla's expert agrees "disclose[s] the same configuration" as the '552 Publication, FOF 188, Tr. 586:11-587:15, does not even disclose a "regulator," much less one with the specific "resistance force" that the Asserted Claim requires. *See* JTX-006, at 27222-227 (PTAB); Tr. 724:24-728:15 (Lewis). The PTAB's decision resulted from a series of exchanges between the examiner and the applicant, which led to the issuance of the '808 Patent. The examiner initially relied on the same logic that Cipla uses here—namely, that the claims (including claim 28) would have been obvious based on a comparison between Figure 15 of the '950 Publication ("O'Leary") and the figures of the '808 Patent. *See* JTX-006, at 27224-26. The PTAB reversed the examiner's decision, holding that the '950 Publication provided insufficient information to determine whether its bobbin 132 (analogous to the '552 Publication's stock bobbin 68) would "necessarily result in incremental movement." *Id.*

Cipla's trial theory compares the '552 Publication's Figure 6 and the '808 Patent's Figure 6A and reaches the same mistaken conclusion as the examiner. Br. 17-23. But as Mr. Anderson was forced to concede, Figure 6 of the '552 Publication is materially the same as Figure 15 of the '950 Publication. FOF 187, 188. Cipla makes the same arguments with respect to the '552 Publication as the examiner did, and likewise fails to show that the relevant figure would "necessarily result in incremental movement." *Id.*

’950 Publication, Fig. 15 (JTX-006)	’552 Publication, Fig. 6 (DTX-152)
	

Having failed to hide the PTAB’s decision from the Court at trial, Cipla devotes a quarter of its brief to fighting a rearguard action against that decision. *See* Br. 17-23, 24-29. Because the ’552 Publication unequivocally did not address the claimed “resistance force,” *supra* §§ V.C.1-2, the Court need not entertain Cipla’s invitation to second-guess the PTAB’s analysis, which only offers yet more reason to reject its theory.

First, Cipla cites Mr. Anderson’s testimony that the ’552 Publication discloses a “regulator” because it depicts “projections [on 70] and a surface for the projections [inside 68] to actually physically engage with.” Br. 20. But as the PTAB noted, the ’950 Publication also disclosed projections or “nubs” (146) and a surface (132); the PTAB deemed this insufficient because it fails to describe how the projections interacted with that surface. *See* FOF 189-190; JTX-006 at 27226 (PTAB Op.).

Second, Cipla argues that Teva’s inventors admitted that the ’552 Publication discloses a “regulator” based on their testimony about an engineering drawing (PTX-231). Br. 22-23, 28-29. Cipla is wrong. Once again, similarities between two sets of figures do not mean they function in the same way. *See* JTX-006 at 27226 (PTAB Op.).[9]

[9] Teva could not have disclosed a regulator in April 2008 because it had not yet invented one. FOF 193-194. The ’552 Publication was filed in April 2008, and describes a prior

Third, Cipla argues that Dr. Lewis's testimony regarding a child's "roundabout" contradicts Teva's statement during prosecution that the claimed "regulator" required more than "resilient resistance." Br. 27-28. Cipla misconstrues Dr. Lewis's testimony. As Teva's Opening Brief explains, Dr. Lewis referred to "roundabouts" in order to explain that forces could operate "*against movement* of the counter display" (as claim 28 requires) without being applied in a direction *opposite* the counter display's movement. D.E. 262, at 41-42; Tr. 408:19-410:22. Dr. Lewis's analogy about the *direction* of force does not relate to the need for "incremental movements." FOF 191.

Finally, Cipla argues that the '552 and '950 Publications provide different disclosures based on scattered language in the '552 Publication. *See* Br. 25-26. Notably, while Cipla's attorneys advance this argument, Mr. Anderson offered no such testimony from the perspective of a POSA. To the contrary, Mr. Anderson conceded that the '552 and '950 Publications "disclose the same configuration." FOF 188; Tr. 586:11-587:15. Dr. Lewis agreed, and the Court should do the same. FOF 188.

VI. Conclusion

For the foregoing reasons, Teva respectfully requests that the Court find that Cipla has failed to prove any Asserted Claim invalid by clear-and-convincing evidence. Teva's opening brief (D.E. 249) further address objective indicia of nonobviousness.

---

art inhaler that Teva (Ivax) developed before beginning the project that led to the claimed "regulator." *See* DTX-162 at Abstract; Tr. 68:7-72:10. Teva did not embark on the latter project until "the end of 2008." Tr. 101:2-4; PTX-216 at 458911, and the drawing Cipla cites was not even created until November 2009. *See* PTX-231 at 462022.

Dated: February 27, 2023

Respectfully submitted,

WALSH PIZZI O'REILLY FALANGA LLP

/s/ Liza M. Walsh

Liza M. Walsh
Katelyn O'Reilly
Selina M. Ellis
Three Gateway Censelinter
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

OF COUNSEL:
David I. Berl
Elise M. Baumgarten
Benjamin M. Greenblum
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.